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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,720	07/18/2005	David John Pritchard	ABL-011.5P US	6344

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

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12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,720	PRITCHARD, DAVID JOHN	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 57-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

DETAILED ACTION

Election Restriction

1. Applicant's election with traverse of the species - Group II (claims 1 and 57-69) in the reply filed on 7/28/08 is acknowledged. The traversal is on the ground(s) that the restriction requirement presented 4/25/08 is identical the requirement on 10/03/07. This argument was carefully considered but not found persuasive because the restriction presented on 4/25/08 was a species election while the restriction on 10/3/07 was directed to independent and distinct inventions.

2. In addition, Applicant argues that the inventions of Group I and Group II represent one method wherein the sample to be used in the method is further defined in claims 57-69. This argument was carefully considered but not found persuasive because the inventions have divergent searches that do totally coextensive. In particular, disease characterizations are not required for Group I.

Further, the invention was previously determined not to be a contribution over the prior art and therefore did not have a special technical feature. See restriction dated 10/3/07. The special technical feature that appears to link claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 57-70, 75, 77, 79-83, 88, and 90-91 is the measurement and differentiation of various forms of factor XIIa (FXIIa). The claims are also directed to the utility of the factor XIIa measurement in disease assessment.

However, factor XIIa detection and differentiation has been taught by the prior art. For example, the reference to Esnouf et al. (Thromb Haemost 2000, Vol.83, pages 874-881) discloses methods for detecting β-factor XIIa and α-factor XIIa with a monoclonal antibody designated mAb 2/215. See abstract. The procedures distinguish α-factor XIIa from the "α-factor XIIa:C1-INH complex" (other forms of factor XIIa). See page 877 – Results.

With respect to factor XIIa's use in disease, it is noted that both Dick et al. (Haemostasis, May 2000, Vol.30, No.1-2, page 92 – Abstract Only) and Kariyawasam et al. (Journal of Hypertension, 2000, Vol.18, No.Suppl.4 pages S24-S25 – Abstract Only) teach factor XIIa measurements in renal and cardiovascular disorders.

Therefore the technical feature recited in claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 57-70, 75, 77, 79-83, 88, and 90-91 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

Accordingly, the species requirement is maintained.

3. Applicant argues that the restriction requirement is contrary to the international standards, however, the U.S. Patent and Trademark Office is not bound by the interpretation of the prior art and claims expounded in the IPER.

4. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 2-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 70, 75, 77, 79-83, 88, and 90-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected elected invention, there being no **allowable** generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/28/08. Currently claims 1 and 57-69 are under consideration.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

7. The information disclosure statements filed 9/30/05 has been considered prior to first action on the merits.

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The use of the trademarks has been noted in this application. (.i.e. TRITON on page 11 line 9, page 13 line 5, and page 103, line 24; EPPENDORF on page 82 line 11; for example). They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Abstract

10. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 57-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and indefinite because it is not clear as to how the method will detect forms of factor XIIa in preference to other forms of factor XIIa. Is it Applicant's intent to mean the method measures forms of factor XIIa in preference to other **factor XII**? If this is not the case, Applicant should clarify the forms that are measured because the instant claims appear to detect and not detect the same forms (all directed to factor XIIa). Appropriate correction is required.

B. Claim 1 is not a proper method claim and is therefore vague and indefinite. Method claims require a contact step, complex formation, and correlation with respect to the intended outcome. Because claim 1 does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Please add method steps, however Applicant is cautioned not to introduce new matter into the claims.

C. Claims 57, 59, 60, 61, 62, 63, and 66 are indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of…" with the use of the conjunction "and" rather than "or" in listing specifies. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 57, 58, 59, 60, 61, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Michael Esnouf (U.S. Patent #5,500,349).

Esnouf discloses procedures to measure factor βXII or factor βXIIa via antibodies that show no substantial binding to factor XII. Esnouf utilizes the same antibodies that are disclosed by the instant specification for differential factor XIIa detections (antibodies 2/215, 201/9, 202/16.1.9). For example, see page 13 of the disclosure. The detected factor XIIa is taught to be useful in various diseases or disorders. The diseases include heart diseases like ischemic heart disease and acute myocardial infarction (AMI). See column 2 lines 40-46. The detected factors are utilized in studying blood coagulation systems and thrombotic disorders. See abstract and column 11 through column 12. Methods of comparing the measured results to controls are also discussed. See column 4 lines 1-11.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

II. Claims 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael Esnouf (U.S. Patent #5,500,349) in view of Coppola et al. (Blood Coagulation & Fibrinolysis, 1996, Vol. 7, No.5, pages 530-535, Abstract Only).

Please see Michael Esnouf as set forth above.

Michael Esnouf differs from the instant invention in not specifically teaching the measurement of factor XIIa in sepsis and disease treatment.

However, Coppola et al. teach procedures for utilizing factor XIIa in sepsis detection and treatment with thrombolytic agents. FXIIa was significantly higher in patients with severe sepsis. The use of the immunoassay of FXIIa permitted a more direct study of the contact phase of blood coagulation in situations in which the coagulation system may play a pathophysiological role. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ FXIIa measurements in sepsis and disease treatments as taught by Coppola et al. in the Factor XIIa detection procedure of Esnouf because Coppola et al. taught that The use of the immunoassay of FXIIa permitted a more direct study of the contact phase of blood coagulation in situations in which the coagulation system may play a pathophysiological role. See abstract.

14. For reasons aforementioned, no claims are allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
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12/8/08

/Lisa V. Cook/
Examiner, Art Unit 1641